

Applicants : Michael Wayne Graham and Robert Norman Rice
Serial No. : 10/646,070
Filed : August 22, 2003
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REMARKS

Claims 48, 110, 114 to 136, 138 to 140, and 145 to 152 were pending in the subject application, of which claims 139, 140, 145, and 150 to 152 were withdrawn. Applicants have herein amended the claims to recite subject matter deemed to be free of prior art on page 18 of the June 9, 2009 Office Action. Applicants have canceled dependent claims 136 and 138, which previously recited the subject matter, without disclaimer or prejudice to Applicants' right to pursue the subject matter of these claims in this or another application.

Accordingly, claims 48, 110, 114 to 135, 139, 140, and 145 to 152 are pending in the subject application, and all claims recite subject matter indicated by the Examiner to be free of prior art.

Support for amendments to claims 48, 110, 120, 121, 126 to 131, 133 to 135, 139, 140, 145 to 150, and 152

The subject application is a continuation of U.S. Serial No. 09/646,807, filed December 5, 2000, now abandoned, as a § 371 national stage of PCT International Application No. PCT/AU99/00195, filed March 19, 1999, which claims priority, *inter alia*, of Australian Provisional Patent Application No. PP2492, filed March 20, 1998 (the "2492 Application"). The new claims are fully supported in the disclosure of the subject application and the disclosures of the 2492 Application.

Applicants have amended claims 48, 110 and 133 (and consequently all pending claims) herein to recite "a sequence of nucleotides that is 50-100 nucleotides in length or 100-500 nucleotides in length," which separates the structural gene regions of the

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synthetic DNA gene. Support for the amendments may be found, *inter alia*, at page 15, lines 13 to 28 of the subject application and at page 19, lines 14 to 26 of the 2492 Application as originally filed.

Applicants have amended claims 48, 110, 128-131, 133 to 135, 139, 140, 145 to 150, and 152 herein to recite "eukaryotic" cell. Support for the language "eukaryotic" may be found, *inter alia*, at page 27, lines 19 to 21 of the subject application; and at page 7, lines 12 to 14, of the 2492 Application as originally filed.

Applicants have amended claims 110, 120, and 126 to align them with the rest of the claims by adding an additional instance of the term "DNA" in claim 110 and rearranging the location of the term "DNA" in claims 120 and 126.

Applicants have amended claims 126 and 127 to recite "the nucleotide sequence of the target gene is not capable of being translated." Support for the amendment may be found, *inter alia*, at page 27, lines 16 to 19 of the subject application; and at page 7, lines 10 to 12, of the 2492 Application as originally filed.

Applicants have amended claims 120 and 121 to correct a grammar issue by replacing "the" with "a."

Information Disclosure Statement

Applicants thank the Examiner for considering the references submitted in the May 11, 2009 Information Disclosure Statements.

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Applicants refer the Examiner to the Supplemental Information Disclosure Statement herein, and respectfully request consideration of all items disclosed.

July 6, 2009 Examiner Interview

On July 6, 2009, Applicants' undersigned representative conducted a telephonic interview with Examiner Brian A. Whiteman in which the parties discussed the implications of the statement made by the Examiner on page 18 of the June 9, 2009 Office Action that "[t]he limitation '50-100 nucleotides in length, or 100-500 nucleotides in length' in claim 138 is free of prior art of record." Applicants thank the Examiner for granting the interview and for his courtesy during the interview.

During the interview, the Examiner reaffirmed the conclusion stated on page 18 of the June 9, 2009 Office Action, and that incorporation of the subject matter into all pending claims would make the claims free of prior art. Furthermore, the Examiner stated that the conclusion on page 18 of the June 9, 2009 Office Action does not depend on the claims reciting "vertebrate animal cell," and holds true for composition of matter claims reciting any eukaryotic cell. The Examiner stated that claims reciting "eukaryotic cell" rather than "vertebrate animal cell" would be free of prior art, so long as the claims also required the limitation indicated on page 18 of the June 9, 2009 Office Action.

All Pending Claims, as Amended, Are Free of Prior Art

On page 18 of the June 9, 2009 Office Action, the Examiner concluded that the limitation "50-100 nucleotides in length, or

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100-500 nucleotides in length" is free of prior art of record. Accordingly, Applicants have amended claims 48, 110 and 133 (and consequently all pending claims) to recite this limitation for the nucleotide sequence that separates the sense gene region from the antisense gene region in the synthetic gene of the claims. Thus, all pending claims are now free of prior art and the anticipation and obviousness rejections set forth in the June 9, 2009 Office Action are moot and are not addressed. However, for the record, Applicants do not concede the correctness of the anticipation and obviousness rejections set forth in the June 9, 2009 Office Action; rather, Applicants have made the amendments herein to expedite allowance of subject matter acknowledged to be free of prior art.

Applicants respectfully request that the Examiner issue a Notice of Allowance for the amended claims without further delay.

Double Patenting Rejections

Claims 48, 110, 114-121, 124-136, 138 and 146-149 were rejected in the June 9, 2009 Office Action on the ground of nonstatutory obviousness-type double patenting as allegedly unpatentable over claims 1-6, 11-15, and 19-21 of U.S. Patent No. 6,573,099 ("the '099 Patent").

In response, to advance prosecution, Applicants have amended the pending claims to recite that a nucleotide sequence of a specific length range separates the sense gene region from the antisense gene region in the synthetic gene. There are no claims in the '099 Patent that specifically recite the length of sequences separating the sense and antisense gene regions of the claimed constructs.

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Applicants note that claim 138 was included in the list of rejected claims, but believe that the Examiner included claim 138 in the nonstatutory double-patenting rejection over the '099 Patent because claim 138 recited in the alternative a length limitation of 10-50 nucleotides. Although Applicants believe that such a length limitation is not obvious from the claims of the '099 Patent, the pending claims, as amended, only recite the 50-100 or 100-500 length limitation, which cannot be obvious from the claims of the '099 Patent. Thus, Applicants submit that the nonstatutory obviousness-type double patenting rejection does not apply to the claims as amended and request that the rejection be withdrawn.

Claims 48, 110, 114-121, 124-136, 138 and 146-149 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as allegedly unpatentable over claims 131-135, 137-147, 149-160, and 162-176 of U.S. Serial No. 10/346,853.

In response, Applicant's respectfully traverse.

Applicants respectfully point out that U.S. Serial No. 10/346,853, relied upon to support the provisional obviousness-type double patenting rejection, is a pending application. Consequently, the claims in the subject application will have an earlier issue date and as such cannot be rejected over later issued claims.

Upon withdrawal of the rejections under 35 U.S.C. §§ 102 and 103 and the nonstatutory obviousness-type double patenting rejection for reasons hereinabove, the pending claims will be rejected solely on the ground of a provisional obviousness-type double

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patenting rejection. Because such provisional rejections rely on a pending application, the rejections should be withdrawn, the pending claims should be confirmed patentable, and any obviousness-type double patenting rejection should be considered if appropriate only in pending applications. See, M.P.E.P. § 804(I)(B)(1).

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Supplemental Information Disclosure Statement

In accordance with the duty of disclosure under 37 C.F.R. § 1.56, Applicants direct the Examiner's attention to the following references which are listed on the Form PTO-1449 (Substitute) attached hereto as **Exhibit A**.

According to 37 C.F.R. § 1.97(c), a Supplemental Information Disclosure Statement filed after the period specified in 37 C.F.R. § 1.97(b) shall be considered if accompanied by the fee set forth in 37 C.F.R. § 1.17(p) or a statement under 37 C.F.R. § 1.97(e). The required fee set forth in 37 C.F.R. § 1.17(p) is one hundred and eighty dollars (\$180.00) and a check including this amount is enclosed.

A copy of item 1 is attached hereto as **Exhibit C**. Copies of items 2 to 7 have not been included in accordance with 37 C.F.R. § 1.98(a)(2)(ii). Copies of the remaining items listed below have been submitted to or provided by the United States Patent and Trademark Office in related patent applications. Applicants attach hereto as **Exhibit B** a table listing locations where a copy of each listed reference may be found. Applicants respectfully direct the Examiner to the Image File Wrapper of the appropriate related application for a copy of the reference.

The Examiner is respectfully requested to make these references of record in the above-identified application by initialing and returning a copy of the enclosed Form PTO-1449 (Substitute).

1. Third party observations under article 115 EPC against European Patent Application EP 98964202.0 in the name of Carnegie Institution of Washington, submitted to the

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European Patent Office on March 24, 2009, attached hereto
as **Exhibit C**;

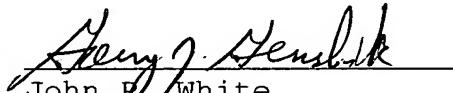
2. Amendment submitted May 11, 2009 in connection with U.S. Serial No. 11/179,504, filed July 13, 2005;
3. Communication issued May 21, 2009 in connection with U.S. Serial No. 11/218,999, filed September 2, 2005;
4. Response to Communication submitted June 22, 2009 in connection with U.S. Serial No. 11/218,999, filed September 2, 2005;
5. Office Action issued May 11, 2009 in connection with U.S. Serial No. 09/287,632, filed April 7, 1999;
6. Office Action issued May 12, 2009 in connection with U.S. Serial No. 11/607,062, filed December 1, 2006;
7. Restriction Requirement issued May 4, 2009 in connection with U.S. Serial No. 11/841,737, filed August 20, 2007;
8. Giering J.C., et al. (2008) "Expression of shRNA from a tissue-specific pol II promoter is an effective and safe RNAi therapeutic," Mol Ther. 16(9):1630-6;
9. Ruiz F, Vayssié L, Klotz C, Sperling L, Madeddu L. (1998) "Homology-dependent gene silencing in Paramecium," Mol Biol Cell. 9(4):931-43;
10. Sánchez Alvarado A, Newmark PA. (1999) "Double-stranded RNA specifically disrupts gene expression during planarian regeneration," Proc Natl Acad Sci U S A. 96(9):5049-54; and
11. Song J., et al. (2004) "Poly(U) and polyadenylation termination signals are interchangeable for terminating the expression of shRNA from a pol II promoter," Biochem Biophys Res Commun. 323(2):573-8.

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If a telephone interview would be of assistance in advancing prosecution of the subject application, Applicants' undersigned attorney invites the Examiner to telephone him at the number provided below.

No fee, other than the \$180.00 for the Supplemental Information Disclosure Statement, is deemed necessary in connection with the filing of this Amendment. However, if any fee is required authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,


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I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to:

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Alexandria, VA 22313-1450


Gary J. Gershik Date
Reg. No. 39,992

EXHIBIT A

Supplemental Information Disclosure Statement

Submitted: July 15, 2009

Serial No. 10/646,070

Filed: April 22, 2003

Applicants: Michael Wayne Graham et al.